RESPONSE TO OFFICE ACTION

I. Double Patenting

The Examiner provisionally rejected claims 1, 3-14, 16, 18, 20, 22-24, 26, and 28-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent Application No. 10/313,643. This rejection is respectfully traversed.

The Examiner stated that although "conflicting claims are not identical, they are not patentably distinct from each other because claims 1-11 of the referenced non-provisional U.S. Patent Application are drawn to a method comprising the same ingredients and essentially the same steps to obtain a method as claimed in the recited claims of instant application. (Office Action, page 3.)

Applicants submit that claims 1-11 of U.S. Patent Application No. 10/313,643 recite methods for increasing endogenous erythropoietin and for treating an erythropoietin-associated disorder. These claims do not relate to any methods for regulating fat metabolism or a fat metabolic process, for achieving fat homeostasis, for treating or preventing obesity, for regulating body weight, for reducing body fat, for inducing weight loss, or for altering expression of a fat regulatory factor, as specifically recited in claims 1, 3-14, 16, 18, 20, 22-24, 26, and 28-31 of the present application. Therefore, claims 1-11 of U.S. Patent Application No. 10/313,643 and claims 1, 3-14, 16, 18, 20, 22-24, 26, and 28-31 of the present application are patentably distinct. Accordingly, Applicants respectfully request withdrawal of the provisional rejection of claims 1, 3-14, 16, 18, 20, 22-24, 26, and 28-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent Application No. 10/313,643.

II. Rejection of claims 1-31 under 35 U.S.C. 103

The Examiner rejected claims 1-33 under 35 U.S.C. 103(a) as obvious over the combined teachings from Edwards et al (U.S. Patent No. 5, 916,898) in view of Muller (EP 0878 480). This rejection is respectfully traversed.

Applicants note that the Examiner has rejected claims 1-33. Applicants acknowledge the Examiner's statement in the Office Action that the claims of groups I and II have been rejoined. (Office Action, page 2.) According to the Restriction Requirement dated 14 June 2006, Group I contains claims 1, 3-14, 16, 18, 20, 22-24, 26, and 28-31 and Group II contains claims 2, 4, 13, 15, 17, 19, 21, 25, and 27.

Therefore, Applicants believe that claims 1-31 are currently pending, and that the Examiner intended to reject claims 1-31 under 35 U.S.C. 103(a) in view of Edwards and Muller, and address this rejection on this basis. If this is not correct, Applicants respectfully request notice and an opportunity to respond.

The MPEP states that "[t]o support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." (MPEP §706.02(j), 8th Edition, Rev. 6, Sept. 2007, pp. 700-48.)

Edwards discloses pharmaceutical compositions comprising phenanthroline derivatives and their use in the treatment of fibroproliferative disease. Edwards neither expressly or impliedly teaches or suggests any method for regulating far metabolism or any method for treating or preventing obesity, nor expressly or impliedly discloses any subject matter relating to fat metabolism, fat homeostasis, fat regulatory factors, obesity, or weight loss as recited in the present claims. As such, Edwards provides no teaching or suggestion that stabilization of HIF α or inhibition of HIF prolyl hydroxylase would be effective at regulating fat metabolism as claimed in the instant application. Therefore, claims 1-31 are nonobvious in view of Edwards.

The deficiencies in the teachings of Edwards are not remedied by Muller. Muller teaches that inhibition of prolyl-4-hydroxylase, and prevention or inhibition of basal membrane formation, provides an effective treatment for neuronal regeneration. Applicants note that Muller does not expressly or impliedly disclose any method for regulating far metabolism or any method for treating or preventing obesity, nor does Muller expressly or impliedly disclose any subject matter relating to fat metabolism, fat homeostasis, fat regulatory factors, obesity, or weight loss as recited in the present claims. Therefore, Muller provides no teaching or suggestion that stabilization of HIF α or inhibition of HIF prolyl hydroxylase would be effective at regulating fat metabolism as claimed in the instant application. Claims 1-31 of the present invention are thus nonobvious in view of Muller.

The Examiner further stated that the "prior art references cited above do not enumerate the regulating of fat metabolism asclaimed [sic] in the instant invention." (Office Action, page 5.) Applicants note that prior to the present invention, stabilization of HIFα and inhibition of HIF hydroxylase activity were not associated in any way with regulating fat metabolism or with treating or preventing obesity. The prior art

references cited above, alone or in combination, fail to provide any degree of predictability or reasonable expectation of success to one skilled in the art to the invention as claimed in the present application. Therefore, Edwards and Muller, singly or in combination, fail to expressly or impliedly teach or suggest the methods recited in claims 1-31 of the instant application. Accordingly, Applicants respectfully request that the rejection of these claims under 35 U.S.C. 103(a) as being obvious over Edwards in view of Muller be withdrawn.

III. Rejection of claims 1-31 under 35 U.S.C. 103

The Examiner rejected claims 1-33 under 35 U.S.C. 103(a) as being unpatentable over Guenzler et al. (WO 03/049686). The Examiner stated that "[c]laims 1-11 of the referenced '686 application are drawn to a method comprising the same ingredients and essentially the same steps to obtain a method as claimed in the recited claims of the instant application." (Office Action, page 6.) This rejection is respectfully traversed.

As noted above, Applicants believe the Examiner intended to reject claims 1-31 under 35 U.S.C. 103(a) as being unpatentable in view of Guenzler. If this is not correct, Applicants respectfully request notice and an opportunity to respond.

The MPEP states that "[t]o support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." (MPEP §706.02(j), 8th Edition, Rev. 6, Sept. 2007, pp. 700-48.)

Guenzler relates, generally, to the discovery that stabilization of HIF α can be achieved by inhibiting hydroxylation of HIF α . Guenzler further relates to methods for treating ischemic disorders by stabilization of HIF α (e.g., by inhibiting HIF hydroxylase activity). Guenzler does not expressly or impliedly teach or suggest any method for regulating fat metabolism, achieving fat homeostasis, treating obesity, regulating body weight, or reducing body fat as recited in the instant claims. Guenzler thus fails to provide any teaching or suggestion that stabilization of HIF α or inhibition of HIF prolyl hydroxylase would be effective at regulating fat metabolism as claimed in the instant application. Claims 1-31 of the present invention are thus nonobvious in view of Guenzler.

10/729,167 filed 04 December 2003 Fourney, et al. Response to Office Action of 22 August 2007

CONCLUSION

In view of the foregoing, Applicants submit that the claims are fully in condition for allowance and request notification to that effect.

The Commissioner is hereby authorized to charge the total of any fee necessary in this communication to Deposit Account No. 50-0811, referencing Docket No. FP0602.2 US. This response is enclosed in duplicate.

Please call Applicants' representative at 650-866-7289 with any questions regarding the present communication or the above-referenced application.

Respectfully submitted,

FibroGen, Inc. 225 Gateway Boulevard

South San Francisco, CA 94080

Date: 22 February 2018

Main: 650.866.7200 Direct: 650.866.7289 Facsimile: 650.866.7292 jnesbitt@fibrogen.com Ву:

James E. Nesbitt, Ph.D.

Reg. No. 54,575